NOV 2 2 2002

K022970

510(k) Summary of Safety and Effectiveness - as required by section 807.92(c)

Date prepared:	September 1, 2002
Submitted by:	Amicas, Inc. 20, Guest St. Boston, MA 02135
Contact:	Patrice Nedelec
Contact email:	pnedelec@amicas.com
Contact Telephone:	617-779-7858
Contact Fax:	617-783-7209 or 617-779-7879
Device Trade Name:	Amicas Light Beam Workstation
Device Common Name:	Picture Archiving Communication System (PACS)
Regulation number:	892.2050
Device Classification:	Class II
Name:	Diagnostic Workstation
Predicate Device:	Voxar Plug'n View 3D, Version 1.0
Predicate Device Manufacturer:	Voxar Limited Bonnington Bond 2 Anderson Pl. Edinburgh, UK EH6 5NP
Predicate Device 510(k) number:	K992654
Date received:	08/09/1999
Decision date:	11/05/1999
Decision:	Substantially equivalent
Panel Code Device reviewed by:	Radiology
Panel Code Device classified by:	Radiology
Product Code:	LLZ
Regulation number:	892.2050
Device Classification:	Class II

Device Description and intended use:

AMICAS Light Beam Workstation (ALBW) is software intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images.
Typical users of ALBW are radiologists, technologists and clinicians.

Technological characteristics:

Feature	ALBW	Voxar Plug'n View 3D version 1.0
Software Only	**Yes**	**Yes**
Image Measurements	**Yes**	**Yes**
Multi-planar reformatting	**Yes**	**Yes**
Volume Rendering	**Yes**	**Yes**
Maximum Intensity Projection	**Yes**	**Yes**
Image editing	**Yes**	**Yes**
Printing	**Yes**	**Yes**
DICOM Images	**Yes**	**Yes**
Lossless JPEG2000 Compression	**Yes**	**No**
Lossy JPEG2000 Compression	**Yes**	**No**

General Safety Considerations

ALBW software and the computer platform that it is installed on together constitute a system for the interpretation of medical image data by trained and qualified professionals. It is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application. Refer to the instruction manuals for your specific computer and display hardware for information regarding installation, calibration and additional safety issues.

The ALBW includes tools for enlarging, highlighting and obscuring portions of an image relative to other portions. Inappropriate application of these tools can result in the obscuration of important anatomy and contribute to an erroneous interpretation. It is the user's responsibility to understand the effect of image manipulation tools and to apply in a manner consistent with the clinical application. The user must review the cautionary statements in the User's guide.

Be sure to limit access to patient data to authorized individuals who are fully trained and qualified to use this equipment.

Testing:

ALBW is tested with reference to its Software Requirements Specifications, as documented in the Verification Procedure included in this 510(k) filing.
Functional testing is an integral part of Amicas, Inc. Product Development process, also included in this filing (see section G)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2002

Mr. Patrice Nedelec
Director, Quality Assurance
and Regulatory Affairs
Amicas, Inc.
20 Guest St.
BOSTON MA 02135

Re: K022970
Trade/Device Name: Amicas Light Beam Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 1, 2002
Received: September 6, 2002

Dear Mr. Nedelec:

This letter corrects our substantially equivalent letter of November 22, 2002, regarding the incorrect address.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

David A. Legan

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022970

Device Name: Amicas Light Beam Workstation

Indications For Use:

The AMICAS Diagnostic Workstation (ADW) is software intended for viewing and diagnostic interpretation of images acquired from CT, MR, CR, DR, US and other DICOM-compliant medical imaging systems when installed on suitable commercial-standard hardware. The ADW receives imaging studies over a network from AMICAS servers or directly from CD with images utilizing both lossless (reversible) and lossy (irreversible) compression. It is the user's responsibility to ensure that monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional format 3-10-98)

Prescription Use ✓

David G. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022970